



AccuPen[®] Handheld Tonometer
PachPen[®] Handheld Pachymeter
AccuPach VI[®] Desktop Pachymeter

When the Pressure's On... The AccuPen® Delivers

The AccuPen® - Handheld Applanation Tonometer
Product Number: 24-3000

Accurate

- Gravity Offset Technology provides precise IOP measurements with less calibration compared to other handheld tonometers.
- Micro strain gauge technology combined with proprietary algorithm provides reproducible results.

Easy-to-Use

- Ergonomic design combined with sighting lines allow for easy visualization of the cornea, facilitating both centralization and perpendicularity.
- Contoured molding with large, visible LCD allows the AccuPen® to be used ambidextrously and fit comfortably in any size hand.

Ready-to-Use

- Eliminates the constant need for "up, down and around" calibration.
- Long lasting lithium battery lasts 4-6 months.

Portability

- Weighs only 3.0 oz.
- Comes with custom, heavy duty traveling case and lanyard for safe transportation.

Versatility

- Fast measurements with patient in any position.
- Frees up valuable office space.

Smarter Software

- Stores and averages nine measurements.
- Built in IOP Correction Calculator adjusts IOP based on corneal thickness.



AccuTip Covers:
Sleeved, sanitized and individually packed
AX9950 - Box of 100
AX11932 - Box of 300

The Next Generation in Pachymetry

The PachPen® - Handheld Pachymeter

Product Number: 24-5100

Accutome's PachPen® is the perfect combination of accuracy, portability and comfort. The superior ergonomic design fits comfortably in any hand, offering a major improvement from other handheld models.

Accurate

- 65 MHz sampling probe ensures precise measurements.
- Uses Digital Signal Analysis to analyze wave patterns and eliminate non perpendicular measurements.

Easy-to-Use

- Ergonomic design, combined with sighting lines, allow for easy visualization of the cornea, facilitating both centralization and perpendicularity.
- Contoured molding with large, visible LCD allows the PachPen® to be used ambidextrously and fit comfortably in any size hand.

Ready-to-Use

- Digital ultrasound analysis eliminates need for calibration.
- Long lasting lithium battery lasts 4-6 months.

Portability

- Weighs only 3.0 oz.
- Comes with custom, heavy duty traveling case and lanyard for safe transportation.

Versatility

- Fast measurements with patient in any position.
- Frees up valuable office space.

Smarter Software

- Stores and averages nine measurements.
- Built in IOP Correction Calculator adjusts IOP based on corneal thickness.



AccuPach VI®

Desktop Pachymeter

Product Number: 24-6200

- Easy-to-use - User-friendly touch-tone screen allows the user to master the AccuPach VI® in minutes.
- Patients are #1 - Revolutionary voice output feature calls out readings, allowing the user to concentrate more on the cornea.
- Superior Accuracy - State-of-the-art digital technology (Accutome's Digital Signal Analysis), combined with a probe sampling of 65 MHz, ensures precise readings.
- USB Interface - Link to computer or printer via USB Memory Stick.
- Confidence - Digital waveform analysis helps to ensure measurements in seconds.
- Flexibility - Adjustable handle/stand allows viewing on different angles.



Specifications

PachPen and Pach VI Specifications

Accuracy: +/- 5 Microns
Weight: 3.0 oz.
Dimensions: 7 ¼" x 1 ¼"
Probe Dimension: 2.5 mm diameter
Measurement Range: 300-999 microns
Power Source: 3.6 V Lithium Battery (*PachPen*)
Medical grade Power Supply (*AccuPach VI*)

AccuPen Specifications

Accuracy: +/- 2mmHg (*compared to Goldman Tonometer*)
Weight: 3.0 oz.
Dimensions: 7 ¼" x 1 ¼"
Transducer Dimensions: 1.0 mm diameter
Measurement Range: 5-60mmHg
Power Source: 3.6 V Lithium Battery

Accutome is your one stop shop for all of your ophthalmic needs.

Accutome Surgical

Diamond Knives, Disposable Metal Knives and Handheld Surgical Instruments.

Accutome Rx

Office Medications and Supplies

Accutome Ultrasound

A-Scans, B-Scans, Pachymeters and Tonometers

Accutome Repair Center

Fast, Reliable Turnaround For Most Brands of Diamond Knives, Handheld Instruments and Ultrasound Equipment.

For Questions Call 1.800.979.2020

Ordering

- Call toll free 800.979.2020
Monday thru Friday 8AM-6PM
- Fax 610.889.3233
24 hours a day, 7 days a week
- Email info@accutome.com
- Visit us on the web at www.accutome.com

Shipping

Ground - via UPS Ground Service

Air- via best method

Saturday - Orders must be placed before 3PM EST
Friday to ensure Saturday delivery

Terms: NET 30 DAYS from invoice date. Payment should be made by check, VISA, MasterCard or American Express



M-1001

3222 Phoenixville Pike, Malvern PA 19355 USA
800.979.2020 • 610.889.0200 • Fax: 610.889.3233
info@accutome.com • www.accutome.com



EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No.**CE 72349****Issued To:**

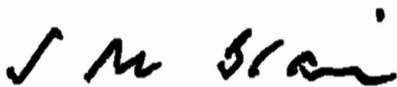
Accutome, Inc.
also trading as Accutome Ultrasound
3222 Phoenixville Pike
Malvern
Pennsylvania
19355
USA

In respect of:

The manufacture of Ophthalmic Diagnostics Biometers.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):



Stewart Brain, Head of Compliance & Risk -
Medical Devices

First Issued: **2003-02-13**

Date: **2018-03-29**

Expiry Date: **2023-02-12**

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Page 1 of 1

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 72349**
 Date: **2018-03-29**
 Issued To: **Accutome, Inc.**
also trading as Accutome Ultrasound
3222 Phoenixville Pike
Malvern
Pennsylvania
19355
USA

Subcontractor:

Service(s) supplied

Emergo Europe
 Prinsessegracht 20
 2514 AP The Hague
 The Netherlands

EU Representative

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EC Certificate - Production Quality Assurance

Certificate History

Certificate No: **CE 72349**
 Date: **2018-03-29**
 Issued To: **Accutome, Inc.**
also trading as Accutome Ultrasound
3222 Phoenixville Pike
Malvern
Pennsylvania
19355
USA

Date	Reference Number	Action
13 February 2003	4416792	First Issue
02 July 2003	4460181	Certificate reissued due to change of address
12 February 2004	4423195	Certificate reissued due to change to company name
28 January 2008	7162453	Certificate Renewal
07 May 2008	7204112	Certificate re-issue to reflect address change.
20 October 2009	7444037	Extension to scope to include Sterile Ophthalmic Blades and addition of EU representative as significant sub-contractor. Addition of 'Steris Isomedix Services, New Jersey' as a significant sub-contractor for Gamma Sterilization.
16 September 2010	7534221	Certificate re-issue due to extension to scope from 'Ophthalmic Ultrasound Diagnostics Biometers' to 'Ophthalmic Diagnostics Biometers'
28 January 2013	7915335	Certificate Renewal
13 July 2015	8359679	Scope reduced by removal of "and Sterile Ophthalmic Blades" and removal of significant subcontractor Steris Isomedix Services Inc.

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

EC Certificate - Production Quality Assurance

Certificate History

Certificate No: **CE 72349**
Date: **2018-03-29**
Issued To: **Accutome, Inc.**
also trading as Accutome Ultrasound
3222 Phoenixville Pike
Malvern
Pennsylvania
19355
USA

Date	Reference Number	Action
Current	8868299	Certificate Renewal. Change of Emergo Europe's address from Molenstraat 15, 2513 BH The Hague, Netherlands to Prinsessegracht 20, 2514 AP The Hague, Netherlands.

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

Doc. No: DOC-24-3000 **Rev. No.:** 01 **Page 1 of 1** **Effective Date:** 05/07/2019

Manufacturer: Accutome, Inc.
(also trading as Accutome Ultrasound, Inc.)

Address: 3222 Phoenixville Pike
Malvern, PA 19355
Tel: 610-889-0200
Fax: 610-889-3233

Authorized Representative: Emergo Europe
Prinsessegracht 20
2514 AP The Hague
The Netherlands
Tel: (31) 70 345 8570
Fax: (31) 70 346 7299

General Applicable Directive:

- Council Directive 93/42/EEC of 14 June 1993 concerning medical Devices
- (MDD 93/42/EEC), as amended by 2007/47/EC.
- Council Directive 2011/65/EU concerning Restriction of Hazardous Substances

Harmonized Standards:

- EN IEC 60601-1
- EN IEC 60601-1-2
- EN 60601-2-37
- EN ISO 14971
- IEC 1157

Device Name: AccuPen

Device Classification: IIa (MDD Annex IX Rule 10)

Route to Compliance: Annex VII coupled with Annex V

EC Certificate: No. CE 72349
Notified Body Number 2797

Description	Part Number
AccuPen	24-3000

Accessories:

Description	Part Number
Battery (2)	24-5101
Lanyard	5100-0050
AccuTip Covers	AX9950
Manual (English)	24-3002
Storage Case with Label	3000-0330
Warning Card	24-3003
Warning Card	24-5108
Screwdriver	24-5107
USB Key w/ Video	24-6215

Accutome, Inc. hereby declares under our sole responsibility that the Accutome product meets the provisions of the Council Directive 93/42/EEC of 14 June 1993 concerning Medical Devices.

Signature:

Date: 7 May 2019

Full Name: Claudia Hill

Position: Quality & Regulatory Manager

SGS

Certificate GB19/964765

The management system of

Keeler Ltd

Clewer Hill Road, Windsor, Berkshire, SL4 4AA, UK

has been assessed and certified as meeting the requirements of

ISO 13485:2016 EN ISO 13485:2016

For the following activities

**Design, Development and manufacture, distribution & service
of Optometric and Ophthalmic medical devices and equipment.**

This certificate is valid from 02 December 2019 until 31 October 2022
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 04 September 2022

Issue 1. Certified since 10 September 1995

Authorised by

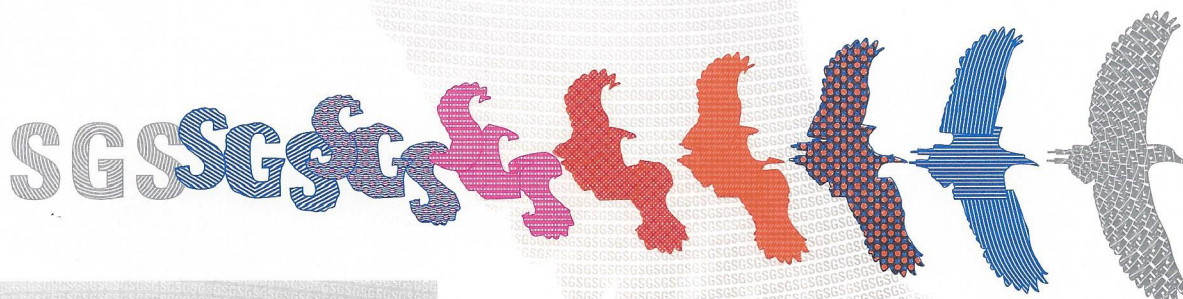
SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

HC SGS 13485 2016 0118

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